

**REMARKS**

**I. Amendments**

The claims page have been amended to begin with "What is claimed is:", as required by the Examiner.

Proposed amended Figures 1-13 have been submitted to correct the Figure labels.

Claims 2, 8-14, 16, 18, 19 and 36 have been amended, and new claims 40 and 41 added, to more clearly and particularly claim the invention, as described in more detail below.

Claims 8-14, 16 and 36 have been amended to replace "vaccine" with --immunogenic composition--. The amendment is supported throughout the specification, specifically at page 40, line 3.

New claims 40 and 41 are dependent on claims 2 and 8 respectively and are drawn to subject matter originally found in claims 2 and 8.

Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

Claims 1-41 are pending. Claims 2, 8-14, 16, 18, 19 and 36 are under examination. The Examiner is requested to also examine new claims 40 and 41, which are dependent on claims 2 and 8 respectively and are drawn to subject matter originally found in claims 2 and 8.

## II. Priority

Claims 2, 8-14, 16, 18, 19 and 36, as amended, and new claims 40 and 41, are drawn to subject matter relating to SEQ ID NOs:1 and 14 (CPN100686). Claims 2, 8-14, 16, 18, 19, 36, 40 and 41 claim priority from U.S. Application No. 60/113,281, filed on December 23, 1998, and are fully entitled to the priority claim. Support for the claims is found throughout U.S. Application No. 60/113,281. Figures 1 and 2 of U.S. Application No. 60/113,281 in particular disclose SEQ ID NOs:1 and 14. Page 9, lines 18-21, of U.S. Application No. 60/113,281 discloses fragments of at least 12 amino acids and preferably at least 20, 50, 75 and 100 amino acids. The Examiner will appreciate that a 12 amino acid fragment corresponds to a nucleic acid fragment of 38 nucleotides, which allows for all three possible open reading frames to translate to a peptide fragment of at least 12 amino acids.

The invention as claimed has been in the possession of Applicants and was fully enabled as of December 23, 1998. Applicants submit that all the pending claims relating to SEQ ID NOs:1 and 14 have an effective filing date of December 23, 1998.

## III. Election/Restriction

A Petition for review of restriction requirement pursuant to 37 C.F.R. §1.144 and the fee are being submitted concurrently with this Response.

The Examiner has made the Restriction requirement Final. The Examiner has rejected Applicants' traversal on the grounds that the claims are unified by a single inventive concept and that there is unity of invention in all the pending claims. The Examiner states that Kalman et al, (GENEMBL, Accession Number AE001641, 12/1/98; reference A57 on PTOL-1449) is novelty-destroying with respect to the technical feature that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

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Applicants submit a printout from the NCBI sequence database showing the Revision history of sequence Accession Number AE001641. The revision history of a sequence on the NCBI database is found at <http://www.ncbi.nlm.nih.gov/entrez/sutils/girevhist.cgi>.

According to the NCBI revision history, "Accession AE001641 was first seen at NCBI on Mar 8 1999 17:32". The Examiner is therefore incorrect in stating that the date of the reference is December 1, 1998. December 1, 1998 is actually the date Accession AE001641 was submitted, not the date it was first seen.

The pending claims relate to SEQ ID NOs:1 and 14 and are fully supported by priority application US 60/113,281 filed December 23, 1998, as stated above. The effective filing date is December 23, 1998. Since Accession AE001641 was first seen *after* the effective filing date of the present application, SEQ ID NOs:1 and 14 do constitute a special technical feature by definition. There is unity present.

The Examiner is requested to review the response to Restriction filed December 4, 2002 and is respectfully urged to examine all the pending claims 1-41.

#### **IV. Double patenting**

The Examiner has provisionally rejected claims 2, 8-14, 16, 18, 19 and 36 under the doctrine of obviousness-type double patenting over the claims of U.S. Application No. 09/886,468. U.S. Application No. 09/886,468 has been abandoned, thus rendering moot this ground for rejection.

#### **V. Rejection Under 35 U.S.C. § 101**

The Examiner has rejected claim 2 under 35 U.S.C. § 101. Applicants traverse this ground for rejection.

Claim 2 has been amended to be drawn to --An isolated and purified nucleic acid molecule--. The amendment is supported at page 11, lines 14-27, of the specification. Withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

**VI. Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)**

Claims 2, 8-14, 16, 18, 19 and 36 of record stand rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse this ground for rejection and submit that the claims, as presently amended, fully comply with the written description requirement.

The present application describes polynucleotides encoding SEQ ID NO: 14 and provide their use for eliciting an immune response. Applicants respectfully submit that the specification further provides a full written description concerning the use of nucleic acid molecules having at least 38 consecutive nucleotides from SEQ ID NO:1, or encoding a fragment of at least 12 amino acids of SEQ ID NO: 14, or amino acid sequences possessing at least 75% identity to SEQ ID NO:14.

Applicants respectfully submit that the nucleic acid molecules of amended claims 2, 8-14, 16, 18, 19 and 36 are defined in clear structural terms, and not solely in functional terms. The present specification specifically recite fragments of SEQ ID NO:14 of at least 12 amino acids in length (page 19, lines 3-4). SEQ ID NO: 14 is 552 amino acid residues in length. The skilled person can immediately envisage every 12-amino acid fragment of SEQ ID NO:14 based on the specification as filed. Thus, there is no question that the specification as filed provides a written description of the claimed fragments.

Independent claims 2, 8 and 9 recite polypeptides possessing at least 75% identity to SEQ ID NO: 14. The specification provides explicit details for calculating sequence

identity and for identifying sequences having a specified degree of sequence identity to SEQ ID NO: 14 (*see e.g.*, page 12, lines 8-23, and page 13, lines 8-21). Applicants respectfully submit that, given the explicit disclosure in the specification of SEQ ID NO: 14 and the significant degree of amino acid sequence identity recited (at least 75%), claims 2, 8-14, 16, 18, 19 and 36 as amended define the invention in such clear, precise, and exact terms as to satisfy the written description requirement.

The Examiner states at page 8 of the Office Action that the specification fails to teach a single variant or homolog of a polypeptide sequence encoded by SEQ ID NO:1. Applicants respectfully disagree. As indicated above, the specification does give explicit details for calculating sequence identity, thereby teaching sequences possessing at least 75% identity to SEQ ID NO: 14.

The Examiner states at page 8 of the Office Action that the claimed polynucleotides do not exist as an invention independent of their function in encoding a putative outer membrane protein. Applicants respectfully disagree. The claimed polynucleotides do exist as an invention independent of their function in encoding a putative outer membrane protein. At least part of their utility lies in encoding polypeptides which elicit an immunogenic response. A 12-amino acid or larger fragment of a polypeptide, or a variant polypeptide, can elicit an immunogenic response without having retained the putative outer membrane of the original sequence (*see* 35 U.S.C. §112, First Paragraph, enablement section below).

The Examiner states at page 9 of the Office Action that the 98kD outer membrane protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The Examiner then goes on to state that there must be some nexus between the structure of a gene sequence and the structure of the protein encodes, and the function of that encoded protein, and that similar function cannot be predicted from the modification of the gene.

With respect, whether the specification characterizes the proteins as 98kD outer membrane proteins is irrelevant. The claims do not recite outer membrane protein

function. The explicit function of the claimed sequences lies in eliciting an immunogenic response (*see* 35 U.S.C. §112, First Paragraph, enablement section below).

The Examiner further states at page 9 of the Office Action that the specification fails to teach the structure or relevant identifying characteristics of a representative number of polynucleotides encoding a representative number of 98kD outer membrane polypeptides, sufficient to allow a skilled person to determine the inventors' possession of the invention.

Applicants respectfully disagree. The principle of a "representative number of species" was established in *University of California v. Eli Lilly and Company* 43 USPQ 2d 1398 (Fed. Cir., 1997). Applicants respectfully submit that the *Eli Lilly* decision is inapplicable to the facts of the present application. In *Eli Lilly*, the court held that disclosure of rat insulin-encoding cDNA does not provide adequate written description of claims generically reciting cDNA encoding vertebrate insulin and mammalian insulin. The single species of vertebrate or mammalian cDNA disclosed did not describe the entire genus of vertebrate or mammalian cDNAs claimed. The present case is different. Applicants claim a nucleic acid molecule encoding a polypeptide defined by a specific amino acid sequence, fragment length, and sequences having a significant degree of sequence identity thereto. The amino acid sequence, variants and fragments thereof are precisely defined in the present claims. This is not an instance of a single species being presented to support the entirety of a genus.

In *Eli Lilly*, the Court stated, at page 1406:

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that

distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Applicants respectfully submit that the present claims define the invention using structural language similar to that of a generic chemical formulae (*i.e.*, by reference to a specific amino acid sequence), a practice cited with approval in *Eli Lilly*. The claims do not merely recite a generic name or functional definition such as "vertebrate insulin cDNA", as in the *Eli Lilly* case. Rather, the skilled person can readily distinguish the formulae of the present claims from other formulae and can immediately identify and envisage many of the species that the instant claims encompass.

The Examiner further comments that conception cannot be achieved until reduction to practice has occurred, and cites a number of cases including *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ 2d 1016, 1021 (Fed. Cir. 1991). In *Amgen*, the Court held that "conception of a generalized approach for screening a DNA library that might be used to identify and clone the EPO gene of then unknown constitution is not conception of a 'purified and isolated DNA sequence' encoding human DNA".

The present application and claims are distinguishable from *Amgen*. The claims recite a specific amino acid sequence and variants having significant identity. This is not an instance of defining a chemical compound by name only and hoped-for function as in *Eli Lilly*, or the mere elucidation of a research plan to obtain a chemical compound described by name only as in *Amgen*. Instead, Applicants' claims recite specific amino acid sequences and clearly defined fragments and variants thereof.

For the foregoing reasons, Applicants respectfully submit that the specification provides a complete written description of the presently pending claims. Reconsideration and withdrawal of the rejections of the claims as lacking written description are therefore respectfully requested.

**VII. Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)**

Claims 2, 8-14, 16, 18, 19 and 36 of record stand rejected under 35 USC § 112, first paragraph, on the grounds that the specification, while being enabling for nucleic acids and vectors comprising SEQ ID NO:1 and host cells comprising such vectors, allegedly does not reasonably provide enablement for the broader genus of all nucleic acids encoding fragments or variants of SEQ ID NO:14.

Applicants respectfully traverse this rejection and submit that the presently amended claims are fully enabled by the specification.

The Examiner appears to contend that there is lack of enablement for all nucleic acid sequences encoding SEQ ID NO:14. Applicants respectfully disagree and submit that the degeneracy of the genetic code is well understood in the art. Thus, with the assistance of a readily available codon usage table, the skilled person could identify without difficulty all nucleic acid sequences that encode SEQ ID NO:14.

The test of enablement is whether the disclosure, when filed, contains sufficient information regarding the claimed subject matter to enable one skilled in the art to make and use the claimed invention without undue experimentation (*see e.g., Mineral Separation v. Hyde*, 242 U.S. 261; *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988); and *United States v. Telectronics, Inc.*, 857 F. 2d 778, 8 USPQ 2d 1217 (Fed. Cir. 1988)).

Variant DNA molecules (*i.e.*, those encoding fragments of SEQ ID NO:14 and variants of SEQ ID NO:14 possessing at least 75% identity thereto) may be prepared by standard DNA mutagenesis techniques as are known in the art, *e.g.*, M13 primer mutagenesis. Details of such techniques are provided in Sanbrook *et al.*, *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor, New York (1989)). Such DNA molecules can be readily inserted into eukaryotic expression vectors as described at page 24, line 3, to page 25, line 32, of the specification. Immunization of test subjects with such variant sequences can be conducted as described at page 16, line 25, to page 18, line 13, of the specification to determine whether such variant sequences encode amino acid



sequences that are capable of inducing an immune response, and preferably a protective immune response, against *Chlamydia*. Thus, the preparation and testing of such sequences can be conducted by the skilled person without undue experimentation, based on the present specification. The present specification provides full details allowing the skilled person to make and use nucleic acids encoding variants of SEQ ID NO:14 that are capable of inducing an immune response against *Chlamydia* and which retain some or all of the specific antigenicity of SEQ ID NO:14.

With respect to nucleic acids encoding fragments of at least 12 amino acid in length from SEQ ID NO:14, Applicants point out that any peptide comprising at least 12 consecutive amino acids from SEQ ID No:14 is understood to work to some extent as an immunogenic fragment. As stated at page 18, lines 20-32, of the specification:

It is an accepted practice in the field of immunology to use fragments and variants of protein immunogens as vaccines, as all that is required to induce an immune response to a protein is a small (*e.g.*, 8 to 10 amino acid) immunogenic region of the protein. Various short synthetic peptides corresponding to surface-exposed antigens of pathogens other than *Chlamydia* have been shown to be effective vaccine antigens against their respective pathogens, *e.g.* an 11 residue peptide of murine mammary tumor virus (Casey & Davidson, Nucl. Acid Res. (1977) 4:1539), a 16-residue peptide of Semliki Forest virus (Snijders *et al.*, 1991. J. Gen. Virol. 72:557-565), and two overlapping peptides of 15 residues each from canine parvovirus (Langeveld *et al.*, Vaccine 12(15):1473-1480, 1994).

Applicants further submit that it is a matter of routine in the art to generate an immune response to peptides of 6 to 15 amino acids, as is evident by the number of groups offering to produce anti-peptide antibodies as a commercial service. The various Web sites include the following:

- (A) The article: Protocol: "Making antibodies to synthetic peptides" is at:  
[http://medicine.ucsd.edu/hypertension/protocol\\_making\\_antibodies\\_to\\_synthetic\\_peptides.htm](http://medicine.ucsd.edu/hypertension/protocol_making_antibodies_to_synthetic_peptides.htm)
- (B) The article "How to make peptide antibody a success..." is at:  
[http://www.eurogentec.com/upload/summer\\_2001/how\\_to\\_make.pdf](http://www.eurogentec.com/upload/summer_2001/how_to_make.pdf)

- (C) The flowchart "At a glance: Peptide-antibody production..." is at:  
[http://www.eurogentec.be/upload/documentation/Protein\\_services/prot\\_serv\\_glan\\_uk.pdf](http://www.eurogentec.be/upload/documentation/Protein_services/prot_serv_glan_uk.pdf)
- (D) A listing of suppliers of Peptide antibody production is at:  
[http://www.biosupplynet.com/cfdocs/products/prod\\_supp.cfm?prod\\_id=2255](http://www.biosupplynet.com/cfdocs/products/prod_supp.cfm?prod_id=2255)
- (E) The page titled "Peptide antibodies" is at:  
[http://www.phoenixpeptide.com/pep\\_antibodies.html](http://www.phoenixpeptide.com/pep_antibodies.html)
- (F) The page titled "Anti-Peptide Antibody programs" is at:  
<http://www.crpinc.com/services/index.html>
- (G) The page titled "Peptides" is at:  
<http://www.qualbio.com/peptides.htm>
- (H) The page titled "Anti-Peptide" is at:  
<http://www.qualbio.com/anti-pep.htm>
- (I) The page titled "Custom Immunology Services" is at:  
[http://www.bioreagents.com/index.cfm/fuseaction/pages.show/name/General\\_Promo](http://www.bioreagents.com/index.cfm/fuseaction/pages.show/name/General_Promo)
- (J) The page titled "Polyclonal Antibody production" is at:  
<http://www.crpinc.com/services/poly.html>

The Examiner will note in particular the protocol (attached) from "http://medicine.ucsd.edu" which states that by using the described routine protocol, synthetic peptide antibodies which recognize the antigen (intact full length molecule, from which the peptide was derived) can be obtained, and that although the antibodies may be of low titer, a usable antibody always result.

In view of the above, Applicants submit that the specification is fully enabling for the nucleic acids encoding SEQ ID NO:14, fragments of at least 12 amino acids and variants having at least 75% identity to SEQ ID NO:14, immunogenic compositions comprising the nucleic acid, and methods of using the above.

In view of the above, withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully requested.

**VIII. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects claims 2, 8-14, 16, 18, 19 and 36 under 35 U.S.C. § 112, second paragraph. Applicants traverse this ground for rejection.

The Examiner rejects claims 2, 8-14, 16 and 36, stating that the metes and bounds of the claimed nucleic acid is unclear. The claims have been amended to refer to a sequence encoding SEQ ID NO:14 which explicitly describes the reading frame.

The Examiner rejects claim 8 as being vague and indefinite with respect to the phrase "at least one first nucleic acid". Claim 8 has been clarified to read --at least one nucleic acid--.

The Examiner rejects claims 8 and 9 for lack of antecedent for "each first nucleic acid". The claims have been amended to recite --the at least one nucleic acid-- for proper antecedent basis.

The Examiner rejects claim 13 as being vague and indefinite with respect to the phrase "second nucleic acid". The claim has been amended to recite --an additional nucleic acid--.

The Examiner rejects claim 14 as being vague with respect to the "additional Chlamydia polypeptide". The claim has been amended to recite --wherein the additional polypeptide is a Chlamydia polypeptide--.

The Examiner rejects claims 18 and 19 with respect to the phrase "complementary or anti-sense sequence of said nucleic acid molecule". The claims have been amended to delete reference to antisense sequences.

In view of the above, Applicants believe that the metes and bounds of claims 2, 8-14, 16, 18, 19 and 36, as amended, can be clearly determined and the claims are clearly defined. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**IX. Rejection of the Claims Under 35 U.S.C. § 102(b)**

**(A) The commercial catalogs**

The Examiner rejects claims 18 and 19 under 35 U.S.C. § 102(b) as being allegedly anticipated by a number of commercial catalogs disclosing random primers, probes and linkers. Applicants traverse this ground for rejection.

The claims have been amended to recite "An isolated and purified" probe or primer. The cited references disclose random primer or probe mixes, in which any particular probe or primer is, by definition, not isolated and purified.

None of the cited references disclose all elements of the claims. That is, none of the cited references disclose: (1) a purified probe of 5 to 100 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary sequence of SEQ ID No:1; or (2) a purified primer of 10 to 40 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary sequence of SEQ ID No:1. In fact, none of the cited references explicitly disclose any sequence that can be compared with the sequences of claims 18 and 19.

If it is the Examiner's intention to reject claims 18 and 19 as being inherently anticipated by the random primer mixes and linkers and kits, Applicants point out that a mere possibility of the primer and probe of claims 18 and 19 having been present in purified form would not constitute inherent anticipation (*Continental Can Company USA, Inc. v. Monsanto Company*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991)).

In view of the above, withdrawal of the rejection of claims 18 and 19 under 35 U.S.C. § 102(b) is respectfully requested.

**(B) Kalman et al (GENEMBL, Accession Number AE001641)**

The Examiner rejects claims 2, 8 and 16 under 35 U.S.C. § 102(b) as being allegedly anticipated by Kalman et al (GENEMBL, Accession Number AE001641). The Examiner states that the reference date is 12/1/98. Applicants traverse this ground for rejection.

Applicants submit a printout from the NCBI sequence database showing the Revision history of sequence Accession Number AE001641. The revision history of a sequence on the NCBI database is found at <http://www.ncbi.nlm.nih.gov/entrez/sutils/girevhist.cgi>.

According to the NCBI, "Accession AE001641 was first seen at NCBI on Mar 8 1999 17:32". The Examiner is therefore incorrect in stating that the date of the reference is December 1, 1998. December 1, 1998 is actually the date Accession AE001641 was submitted, not the date it was first publicly available.

As shown in the preceding section concerning priority, the pending claims relating to SEQ ID NOs:1 and 14 are fully supported by priority application U.S. No. 60/113,281, filed on December 23, 1998, specifically at Figures 1 and 2 which disclose SEQ ID NOs:1 and 14. Vaccine vectors and immunogenic compositions are described throughout U.S. No. 60/113,281, specifically at page 5, lines 9-23, page 11, line 27 to page 12, line 3, and page 13, line 28 to page 17, line 30. The claimed priority date is therefore December 23, 1998.

Since the cited reference was first seen after the claim date of the present application, Kalman et al (GENEMBL, Accession Number AE001641) does not

anticipate claims 2, 8 and 16. Withdrawal of the rejection of claims 2, 8 and 16 under 35 U.S.C. § 102(b) is respectfully requested.

**X. Concluding Remarks**

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

The Petition for Extension of Time pursuant to 37 CFR § 1.136 and the fee are being submitted concurrently with this Response. If a fee is required for an extension of time which is not accounted for above, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

Dated: *June 26, 2003*



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

2. A ~~An~~ isolated and purified nucleic acid molecule comprising a nucleic acid sequence selected from any one of:

- (a) SEQ ID No: 1;
- (b) a sequence which encodes a polypeptide ~~encoded by SEQ ID No: 1~~ as set forth in SEQ ID No:14;
- (c) ~~a sequence comprising~~ at least 38 consecutive nucleotides from SEQ ID No: 1;
- (d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to ~~the polypeptide encoded by SEQ ID No: 1~~ SEQ ID No:14; and
- (e) a sequence comprising at least 100 consecutive nucleotides from a nucleic acid sequence of (b).

8. A ~~vaccine~~ An immunogenic composition comprising a vaccine vector and at least one ~~first~~ nucleic acid selected from any one of:

- (i) SEQ ID No: 1;
- ~~(ii) a nucleic acid sequence which encodes a polypeptide encoded by SEQ ID No: 1;~~
- ~~(iii)~~ (ii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from ~~any one of the nucleic acid sequences of (i) and (ii)~~ SEQ ID No:1;
- ~~(iv)~~ (iii) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to ~~the polypeptide encoded by SEQ ID No: 1~~ SEQ ID No:14;
- ~~(v)~~ (iv) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in SEQ ID No: 14; and
- ~~(vi)~~ (v) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No: 14; and
- ~~(vii) a nucleic acid sequence which encodes a polypeptide as defined in (i) to (v) or an immunogenic fragment as defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (v) or the corresponding fragment of (vi);~~

wherein ~~each first~~ the at least one nucleic acid is capable of being expressed.

9. ~~A vaccine~~ An immunogenic composition comprising a vaccine vector and at least one ~~first~~ nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

- (a) a first polypeptide selected from any one of:
- (i) ~~a polypeptide encoded by SEQ ID No: 1;~~
  - (ii) ~~a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: 1;~~
  - (iii) (i) a polypeptide which is at least 75% identical in amino acid sequence to ~~the polypeptide encoded by SEQ ID No: 1~~ SEQ ID No: 14;
  - (iv) (ii) a polypeptide whose sequence is set forth in SEQ ID No: 14; and
  - (v) (iii) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No: 14; and
  - (vi) ~~a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and~~

and,

- (b) a second polypeptide;

wherein ~~each first~~ the at least one nucleic acid is capable of being expressed.

10. The ~~vaccine~~ immunogenic composition of claim 9 wherein the second polypeptide is a heterologous signal peptide.

11. The ~~vaccine~~ immunogenic composition of claim 9 wherein the second polypeptide has adjuvant activity.



12. The ~~vaccine~~ immunogenic composition of ~~any one of~~ claim 8 wherein each ~~first of the at least one~~ nucleic acid is operatively linked to one or more expression control sequences.

13. ~~A vaccine according to~~ The immunogenic composition of claim 8 wherein each ~~first~~ nucleic acid is expressed as a polypeptide, and wherein the ~~vaccine immunogenic composition further~~ comprises ~~a second~~ an additional nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by the ~~first~~ nucleic acid defined in claim 8.

14. The ~~vaccine according to~~ immunogenic composition of claim 13 wherein the ~~second nucleic acid encodes an~~ additional polypeptide is a *Chlamydia* polypeptide.

16. A pharmaceutical composition comprising ~~a vaccine~~ the immunogenic composition according to claim 8 and a pharmaceutically acceptable carrier.

18. An isolated and purified probe of 5 to 100 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary ~~or anti-sense~~ sequence of ~~said nucleic acid molecule~~ SEQ ID No:1.

19. An isolated and purified primer of 10 to 40 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary ~~or anti-sense~~ sequence of ~~said nucleic acid molecule~~ SEQ ID No:1.

36. A method for preventing or treating *Chlamydia* infection comprising administering to a patient an effective amount of:

- (a) ~~a~~ the nucleic acid according to claim 2;
- (b) ~~a vaccine~~ an immunogenic composition comprising a vaccine vector and at least one ~~first~~ nucleic acid according to claim 2;
- (c) a pharmaceutical composition comprising ~~a~~ the nucleic acid according to claim 2 and a pharmaceutically acceptable carrier;

(d) a polypeptide encoded by a nucleic acid ~~according to claim 2; or~~ sequence selected from any one of:

- (i) SEQ ID No: 1;
- (ii) a sequence which encodes a polypeptide as set forth in SEQ ID No:14;
- (iii) at least 38 consecutive nucleotides from SEQ ID No: 1;
- (iv) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to SEQ ID No:14; and
- (v) a sequence comprising at least 100 consecutive nucleotides from a nucleic acid sequence of (ii);

or,

(e) an antibody against a the polypeptide ~~encoded by a nucleic acid according to claim 2~~ defined in (d).